DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

8/4/97 633

WARNING LETTER

97-PHI-34

July 16, 1997

GEN. SPEC.
RELEASE
F# _____ DATE 7/25/97
Reviewed by:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Hughey (Bobby) P. Weyandt, Owner
RD #2
P.O. Box 1206
Claysburg, Pennsylvania 16625

Dear Mr. Weyandt:

On February 4, 1997, your cattle dealing business, located at RD #2 in Claysburg, Pennsylvania was visited by Food and Drug Administration (FDA) investigator Robert T. Vaughn in response to a United States Department of Agriculture (USDA) report regarding an illegal drug residue in a calf you offered for sale and slaughter for human food. Additional investigation by the Food and Drug Administration at the slaughterhouse, [redacted] has revealed serious violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about December 3, 1996 your firm delivered a calf, back tag 74VH1774, for sale for slaughter for human food at [redacted] United States Department of Agriculture (USDA) analysis of tissue samples collected from the animal identified the presence of 3.10 ppm (parts per million) gentamicin in the kidney tissue. Gentamicin is not approved for use in dairy cattle, and therefore, there is no tolerance for the presence of this drug edible bovine tissue. The presence of gentamicin in edible tissue from your animals causes the food to be adulterated under Section 402(a)(2)(D) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

Additionally, we are aware from review of USDA records and from information gathered during our inspection that since November 29, 1996 you have delivered the following calves for slaughter for human food to [redacted] United States

Department of Agriculture (USDA) testing has revealed violative drug residues in the edible tissues of the these animals as follows:

USDA Sample #	ID	Slaughter Date	Drug Residue/tissue (ppm)
342004	74PF8968	11/29/96	4.00 ppm streptomycin/kidney
342006	23MO3861	12/4/96	0.07 ppm penicillin/liver 1.70 ppm gentamicin/liver 7.20 ppm gentamicin/kidney
342019	no tag	12/23/96	42.00 ppm neomycin/kidney
342018	74PH5442	12/23/96	45.00 ppm neomycin/kidney
342022	74PJ1008	1/6/97	21.00 ppm neomycin/kidney
342027	no tag	1/30/97	7.00 ppm streptomycin/liver 4.00 ppm streptomycin/muscle
342035	no tag	2/14/97	2.90 ppm streptomycin/kidney
328741	74PH9024	5/8/97	27.00 ppm neomycin/kidney

We are also aware of an animal with ear tag "143," and other tags "23MO," and "NYN711149" which you delivered for slaughter for human food at [redacted] on or about March 31, 1997. USDA testing revealed the presence of 0.94 ppm and 0.16 ppm penicillin in the liver and kidney tissues of this animal.

The tolerance for presence of the drugs listed above in edible bovine tissue are as follows: penicillin, 0.05 ppm; streptomycin, 2.0 ppm; and neomycin, 7.2 ppm (kidney tissue). The presence of these drugs in the edible tissues from your animals at the concentration levels detected renders the food from the animals to be adulterated under Section 402(a)(2)(D) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

Our investigation also found that you hold animals under conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for assuring that animals you deliver for slaughter for human food have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from

animals held under such conditions is adulterated.

Our investigation also found that you were unable to provide records with respect to calves with back tags 74VH1774, 74PH5442, 74PJ1008, 74PF8968, and 23MO3861.

The violations listed above are not intended to be all inclusive. It is your responsibility to assure that your operations are in compliance with the law. As a livestock dealer or purchaser of animal, you are frequently the individual who introduces or offers for introduction into interstate commerce, an adulterated animal. As such, you share responsibility for violating the Federal, Food, Drug, and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1) implementing a system to identify the animals you purchase with records to establish the traceability to the source of the animal;

2) implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and,

3) if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animal then it should not be offered for human food, and be clearly identified and sold as a medicated animal.

As a cattle dealer/hauler it is your responsibility to assure that the animals you offer for slaughter have not been treated with unapproved veterinary drugs, or if the drugs are approved, that the levels do not exceed established limits. Animals treated with medications must be withheld from slaughter for the appropriate time period.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you purchased a medicated cow and subsequently sold the animal to a slaughterhouse that ships beef in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reasons for the delay and the timeframe in which correction will be achieved. Please include copies of any available documentation demonstrating that correction has been accomplished.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Very Truly Yours,

Diana J. Kolaitis
District Director
Philadelphia District

jci

cc: Dr. Max A. Van Buskirk, Director
PA State Bureau of Animal Industry
Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17120

cc: Dr. F.R. Rellosa
USDA Northeast Regional Office
701 Market Street
2B South
Mellon Independence Center
Philadelphia, PA 19102-1516